EPA Reg. No. 68451-1
Vol. 1

EPA REG. NO.

Date of Application	ACTION CODE	RECORD NO./ REF. NO.	EVENT	RESPONSE DATE	RESPONSE CODE
8-11-93	165	452561	Toxic data submitted w/38(Cotton	11-6-95	37
8-22-95	166	494860		5-2-96	16
8-21-95	166	494967		5-2-96	16
5-13-96	166	506323	Revised Labeling per 5/2/96 ltr.	5-31-96	17
6-16-97	360	525902	Revised Label re: PRN 96-6	10-17-97	17

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 20 2003

Ms. Mary K. Hagler, MS
Regulatory Specialist - Pharmaceuticals
Intervet, Inc
405 State Street, P.O. Box 318
Millsboro, DE 19966

Subject: Amendment - Revised First Aid Statements
Deltamethrin 4% Collar
EPA Registration No. 68451-1
Your Submission Dated May 20, 2003

Dear Ms. Hagler:

The amendment referred to above, submitted in connection with registration under section 3 (c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable, subject to the comments listed below.

Under the "Precautionary Statements" section, move the statements "Do not open...with this collar" and the paragraph beginning "Do not use on puppies under . . .etc" to the "Directions for Use" section of your label.

A stamped copy of the label is enclosed for your records. If you have any questions, please call Dr. William Sproat of my team at 703-308-8587.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Kills Fleas and Ticks for up to 6 Months
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (*including deer ticks which may carry Lyme disease*)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
405 State Street
Millsboro, DE 19966

Product of France

ACCEPTED
AUG 20 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 68451-1

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:
Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING::	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
For incidents involving **HUMANS, call 1-800-680-9206** For incidents involving **ANIMALS, call 1-800-548-2423** Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*) and deer ticks (*Ixodes scapularis* and *Ixodes pacificus)* which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX Universal Product Code Number (Bar Code) Product of France

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
68451-1	George Larocca	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Deltamethrin 4% Collar		

5. Name and Address of Applicant *(Include ZIP Code)*

Intervet Inc.
405 State St; P.O. Box 318
Millsboro, DE 19966

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The purpose of this submission is to revise the storage and disposal statements for the Deltamethrin 4% collar label as required by PR Notice 2001-6.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	(302) 934-4340

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals
4. Typed Name	**5. Date**
Mary K. Hagler	20 May 2003

300-WS

AKZO NOBEL

(302) 934-4340

20 May 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: George Larocca
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar
EPA Reg. No. 68451-1

Dear Dr. Larocca,

In accordance with PR Notice 2001-6, enclosed is an amendment of the disposal instructions for the Deltamethrin 4% Collar label (EPA Registration # 68451-1) for your review and approval.

On 14 March 2003, Intervet Inc. submitted an amendment for the First Aid statements for the Deltamethrin 4% Collar label. This amendment is still under review at EPA. The enclosed label includes the proposed First Aid statements from the amendment submitted 14 March 2003 as well as the updated disposal statements.

A completed EPA Form 8570-1 is enclosed as well as a 3 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 3 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler

Mary K. Hagler, MS
Regulatory Specialist – Pharmaceuticals
Intervet Inc.

Enclosure

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-6087

PESTICIDE REGISTRATION ACTION TRACKING SYSTEM (PRAT)
CODING FORM

IN PROCESSING INFORMATION

Submission Bar Code: S636181 ID Number: 68451-1 Action Code: 300

PM Team: 03 Reviewer: D. SPROAT Due Date: 8 / 19 / 03

Date on Application: 5 / 20 / 03

EPA Received Date: 5 / 21 / 03

PM Received Date: 5 / 27 / 03

Chemical Code (1): _____ Chemical _____

Chemical Code (2): _____ Chemical _____

Proposed Use: Update per PR Notice

Description of Action: _____

Related Actions: _____

OUT PROCESSING INFORMATION

Response Code: _____ Response Date: ____/____/____

75-Day Response:	Yes_____	No_____	MOS: (1)	Cite All
CRP:	Yes_____	No_____	(4)	Not Applicable
Restricted Use	Yes_____	No_____	(8)	Selective
Exclusive Use:	Yes_____	No_____		
Manufacturing Use:	Yes_____	No_____		

Conditional Registration: Data Required

Guideline No._____ Due Date: ____/____/____

Guideline No._____ Due Date ____/____/____

Comments:

A

B

AKZO NOBEL

(302) 934-4340

14 March 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: George Larocca
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar
EPA Reg. No. 68451-1

Dear Dr. Larocca,

In accordance with PR Notice 2001-1, enclosed is an amendment of the First Aid statements for the Deltamethrin 4% Collar label (EPA Registration # 68451-1) for your review and approval.

A completed EPA Form 8570-1 is enclosed as well as a 5 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 5 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler

Mary K. Hagler, MS
Regulatory Specialist – Pharmaceuticals
Intervet Inc.

Enclosure

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-4292

A B

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060, Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 292637

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
68451-1	George Larocca	☐ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Deltamethrin 4% Collar	03	

5. Name and Address of Applicant *(Include ZIP Code)*

Intervet Inc.
405 State St; P.O. Box 318
Millsboro, DE 19966

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
● Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The purpose of this submission is to revise the first aid statements for the Deltamethrin 4% collar label as required by PR Notice 2001-1.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	(302) 934-4340

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signeture	3. Title	
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	
4. Typed Name	**5. Date**	
Mary K. Hagler	14 Mar 2003	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
292637

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	FMA	☐ None ☐ Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
● Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) of Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper Glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
8. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
292637

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM# 03	☐ New ☐ Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Intervet Inc./68451-1	George Larocca	☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
Intervet Inc./ Deltamethrin 4% Collar		

5. Name and Address of Applicant *(Include ZIP Code)*

Intervet Inc.
405 State St.; P.O. Box 318
Millsboro, DE 19966

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

NOTIFICATION
MAR 29 2002

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Revision: Revision of marketing claim per PR Notice 98-10 (see attached draft label for proposed changes). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 , and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	(302) 934-4340

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals
4. Typed Name	5. Date
Mary K. Hagler	21 March 2002

SFG 7/25/02

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

Instructions: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific Instructions: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

Section I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from the party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3(c) 3(b) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar, or identical to other pesticide products that are currently registered with the EPA. In order for you application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

Section II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by . . . "; "reregistration submission"; "general label revision of use directions." Attach a separate page is additional space is needed.

Section III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of the Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

Section IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory
6. EPA Use only

NOTIFICATION

MAR 2 9 2002

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

→Kills Fleas and Ticks for up to 6 Months←
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (*including deer ticks which may carry Lyme disease*)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
→See Back for additional Precautionary Statements←

Adjustable – One Size Fits All

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
405 State Street
Millsboro, DE 19966

Product of France

Page 1 of 2
21 March 2002

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132
FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. ➔ Collar will also kill ticks for up to 6 months. ← Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*) and deer ticks (*Ixodes scapularis* and *Ixodes pacificus)* which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

21 March 2008

AKZO NOBEL

(302) 934-4340

21 March 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Company #: 54382). The label was previously approved per EPA letter dated 17 November 1998 and modified via notification dated 21 Dec 2001.

1. The following text, consistent with statements on page 2 of the label, is being added to page 1 of the label:

   Kills Fleas and Tick for up to 6 months

2. The following statement is being added to page 1 of the label:

   See Back for additional Precautionary Statements

2. The following statement is being added to page 2 of the label:

   Collar also kills ticks for up to 6 months.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes of the label are underlined, highlighted and bracketed with arrows (→←). In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler

Mary K. Hagler, MS
Regulatory Specialist – Pharmaceuticals
Intervet Inc.

Enclosure

intervet

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-4292

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
- ☐ Amendment
- ☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: Intervet Inc./68451-1
2. EPA Product Manager: George Larocca
3. Proposed Classification: ☐ None ☐ Restricted
4. Company/Product (Name): Intervet Inc./ Deltamethrin 4% Collar
PM#:
5. Name and Address of Applicant *(Include ZIP Code)*:
Intervet Inc.
405 State St.; P.O. Box 318
Millsboro, DE 19966
☐ *Check if this is a new address*
6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- ☐ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☒ Notification - Explain below.
- ☐ Final printed labels in repsonse to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Revision: Revision of marketing claim per PR Notice 98-10 (see attached draft label for proposed changes). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 , and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) Retail Container:
5. Location of Label Directions: ☐
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	(302) 934-4340

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature: Mary K. Hagler
3. Title: Regulatory Specialist - Pharmaceuticals
4. Typed Name: Mary K. Hagler
5. Date: 21 March 2002

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Intervet Inc./68451-1	George Larocca	☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
Intervet Inc./ Deltamethrin 4% Collar		

5. Name and Address of Applicant *(Include ZIP Code)*

Intervet Inc.
405 State St.; P.O. Box 318
Millsboro, DE 19966

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Revision: Revision of marketing claim per PR Notice 98-10 (see attached draft label for proposed changes). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 , and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	(302) 934-4340

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received (Stamped)

2. Signature	3. Title	
Mary K. Hagler	Regulatory Specialist - Pharmaceuticals	
4. Typed Name	5. Date	
Mary K. Hagler	21 March 2002	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

→Kills Fleas and Ticks for up to 6 Months←
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (*including deer ticks which may carry Lyme disease*)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
→See Back for additional Precautionary Statements←

Adjustable – One Size Fits All

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
405 State Street
Millsboro, DE 19966

Product of France

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:
Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID
IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132
FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. ➔Collar will also kill ticks for up to 6 months.← Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*) and deer ticks (*Ixodes scapularis* and *Ixodes pacificus)* which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

AKZO NOBEL

(302) 934-4340

21 March 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Company #: 54382). The label was previously approved per EPA letter dated 17 November 1998 and modified via notification dated 21 Dec 2001.

1. The following text, consistent with statements on page 2 of the label, is being added to page 1 of the label:

   Kills Fleas and Tick for up to 6 months

2. The following statement is being added to page 1 of the label:

   See Back for additional Precautionary Statements

2. The following statement is being added to page 2 of the label:

   Collar also kills ticks for up to 6 months.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes of the label are underlined, highlighted and bracketed with arrows (→←). In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler

Mary K. Hagler, MS
Regulatory Specialist – Pharmaceuticals
Intervet Inc.

Enclosure

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-4292

Please Read All Instructions Before Completing this Form (*Form must be typed*) Form Approved. OMB No. 2070-0044. Approval Expires 1-31-96

285847

36 h 2 - 3

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
401 M Street SW
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
4 68451-18	0 2382

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)	Distributor Product Name
Deltamethrin 4% Collar	Preventef-D Flea & Tick Collar for Dogs

Name and Address of Distributor (Type; include ZIP code)
Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for ...," distributed by..."; or sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Michelle Foster, Registration Specialist

Date: 5/14/02

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: L. Lee Whaley

Date: 16 May 2002

EPA Form 8570-5 (Rev. 2-92) Previous editions are obsolete

5.22.2002

TOTAL P.02

Please Read All Instructions Before Completing this Form *(Form must be typed)* **Form Approved. OMB No. 2070-004. Approval Expires 1-31-95**

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
401 M Street SW
Washington, DC 20460

284719
36A 2-3

EPA Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the Distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
4 68451-18	9 4758

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Deltamethrin 4% Collar	**Adams Delta Force Tick Collar for Dogs**

Name and Address of Distributor *(Type; include ZIP code)*

Pet Chemicals
P.O. Box 18993
Memphis, TN 38181

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered product.
3. The labelling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for..", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Bill Washburn, Product Development & Regulatory Affairs Manager

Date: 9/28/01

Registrant

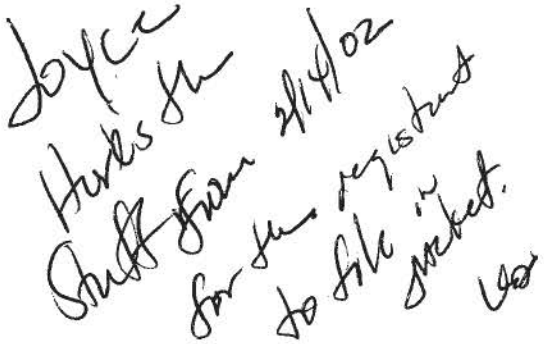
I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: S. Lee Whaley, Manager, Regulatory Affairs - Pharmaceuticals

Date: 15 March 2002

EPA Form 8570-5 (Rev.2.92) Previous editions are obsolete.

3.19.2002


Joyce
Hurley
Stuff from 2/14/02
for the registrant
to file in
packet.
Lee

Telefax Transmittal
Cover sheet

Page 1 of 7

AKZO NOBEL

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966
(302) 934-8051

February 14, 2002

7...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
Mrs. Linda Arrington	U.S. Environmental Protection Agency	703-305-6920

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
S. Lee Whaley, MS Manager, Regulatory Affairs – Pharmaceuticals	Intervet Inc., Regulatory Affairs	Fax: 302-934-4209 Phone: 302-934-4385

RE: Deltamethrin 4% Collar – EPA Registration #68451-1 (Notification Submitted 21 Dec 2001)

Dear Mrs. Arrington:

As we discussed today, please find attached two EPA letters (both dated 14 March 2001) regarding the change of name and ownership of company numbers 68451 and 54382 from Hoechst Roussel Vet to Intervet Inc. Both company numbers now refer to:

Intervet Inc.
405 State Street, P.O. Box 318
Millsboro, DE 19966-0318.

As we discussed, Intervet Inc. is the primary registrant of Deltamethrin 4% Collar (EPA Registration #68451-1) and, as such, Item 1 of the Form 8570-1 Notification submitted 21 December 2001 should have referenced "68451-1" instead of "54382/68451-1". I apologize for any confusion this may have caused. Thank you once again for the notification acknowledgement sent on 14 January 2002. Please feel free to contact me should you have any further questions.

Sincerely,

S. Lee Whaley

S. Lee Whaley, MS
Manager, Regulatory Affairs – Pharmaceuticals
Intervet Inc.

Intervet

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 14, 2001

Mr. Bryan Gathagan
Vice President, Information & Control
Intervet, Inc.
405 State Street, PO Box 318
Hillsboro, DE 19966-0318

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Mr. Gathagan:

Subject: Change of Name and Ownership of Company Number 68451

Pursuant to your letter and agreement of February 7, 2001, we have approved the change in name and ownership of Hoechst-Roussel Vet, company number 68451.

Our records are being amended to show the registrant and Agent under company number **68451** as follows:

Intervet, Inc.
405 State Street; PO Box 318
Millsboro, DE 19966-0318

Authorized Representative: **Bryan Gathagan**
(302) 934-8051

The effective date of this change is the date of this letter.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Page 4 of 7

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker

Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: Mr. Brett Whitehead
Vice President of Animal Health Business Unit
Hoechst-Roussel Vet
Perryville Corporate Park; PO Box 4010
Clinton, NJ 08809-4010

Page 5 of 7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 14, 2001

Mr. Bryan Gathagan
Vice President, Information & Control
Intervet, Inc.
405 State Street, PO Box 318
Hillsboro, DE 19966-0318

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Mr. Gathagan:

Subject: Change of Name and Ownership of Company Number 54382

Pursuant to your letter and agreement of February 7, 2001, we have approved the change in name and ownership of Hoechst-Roussel Vet, company number 54382.

Our records are being amended to show the registrant and Agent under company number **54382** as follows:

Intervet, Inc.
405 State Street; PO Box 318
Millsboro, DE 19966-0318

Authorized Representative: **Bryan Gathagan**
(302) 934-8051

The effective date of this change is the date of this letter.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker

Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: Mr. Brett Whitehead
Vice President of Animal Health Business Unit
Hoechst-Roussel Vet
Perryville Corporate Park; PO Box 4010
Clinton, NJ 08809-4010

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
[redacted]/68451-1	George Larocca	☐ None ☐ Restricted
4. Company/Product (Name) Intervet Inc./ Deltamethrin 4% Collar	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* Intervet Inc. 405 State St.; P.O. Box 318 Millsboro, DE 19966 ☐ *Check if this is a new address*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

NOTIFICATION
JAN 14 2002

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of minor changes to the label front panel, per PR Notice 98-10 (see attached draft label for proposed changes). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 , and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
S. Lee Whaley	Manager, Regulatory Affairs - Pharma	(302) 934-4385

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
S. Lee Whaley	Manager, Regulatory Affairs - Pharmaceuticals
4. Typed Name S. Lee Whaley	5. Date 21 December 2001

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 17 1998

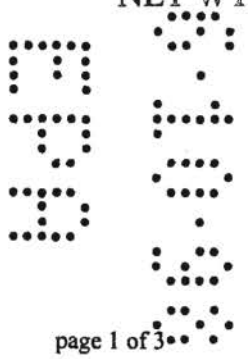
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 68451-1

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 1.1 oz



Hoechst Roussel Vet SA
102 route de Noisy
93235 Romainville, France

20 May 1998

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. ~~Drink one or two glasses of water and induce vomiting by touching back of throat with finger.~~ Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL:
1-800-228-5635, ext. 132
FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide- release technology. Maximum effectiveness may not occur for 2 ~~–3~~ weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*) and deer tick (*Ixodes sp.*) which may carry the Lyme disease. Collar kills and repels mosquitoes (*Aedes aegypti*) and prevents them from feeding. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle-and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

NOTIFICATION

JAN 1 4 2002

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (*including deer ticks which may carry Lyme disease*)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
405 State Street
Millsboro, DE 19966

Product of France

Page 1 of 2
21 Dec 2001

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:
Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID
IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132
FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*) and deer ticks (*Ixodes scapularis* and *Ixodes pacificus)* which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

AKZO NOBEL

(302) 934-4385

21 December 2001

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

NOTIFICATION

JAN 14 2002

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., ~~Company #: 54382~~). The label was previously approved per EPA letter dated 17 November 1998.

1. The following text, consistent with statements on page 2 of the label, are being added to page 1 of the label:

   LONG LASTING PROTECTION FOR UP TO 6 MONTHS
   Kills Ticks *(including deer ticks which may carry Lyme disease)*
   ALSO KILLS FLEAS

2. The following statement is being added to page 1 of the label:

   Adjustable – One Size Fits All

3. The statement, "See Side Panel for additional Precautionary Statements" is revised to read:

   "See Insert or Side Panel for additional Precautionary Statements"

Note also that the net wt. is being revised from 1.1 oz. to 0.9 oz. to better reflect the weight of the collar.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes to page 1 of the label are underlined, highlighted and bracketed with arrows (→←). Note that there are no changes to page 2 of the label. In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4385) or e-mail (lee.whaley@intervet.com) should you have any questions.

Sincerely,

S. Lee Whaley

S. Lee Whaley, MS
Manager, Regulatory Affairs – Pharmaceuticals
Intervet Inc.

Enclosure

Intervet

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-4292

Please Read All Instructions Before Completing this Form *(Form must be typed)* **Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95**

EPA

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

2483445

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
EPA Reg. No. 68451-1 8	54382 7

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Deltamethrin 4% Collar	Deltamethrin 4% Collar

Name and Address of Distributor *(Type; include ZIP code)*

Hoechst Roussel Vet
30 Independence Blvd., Box 4915
Warren, NJ 07059

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Jane Kingett, Registration Specialist — Jane Kingett — Date: 9 Oct 1998

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: John Lauber — Agent for Hoechst Roussel Vet S.A. John J. Lauber, Manager, Product Reg. — Date 9 Oct 1998

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. 10.20.98 White - EPA

*U.S. GPO: 1997-417-473/61206

Please read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB No. 2070-0044. Approval Expires 8-31-97

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

251145
1A 3-2

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

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This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
4 68451-18	3 2781

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
DELTAMETHRIN 4% COLLAR	HAPPY JACK NOVATION™ FLEA & TICK COLLAR FOR DOGS

Name and Address of Distributor *(Type; include ZIP code)*

HAPPY JACK INC
P.O. BOX 475
HIGHWAY 258 SOUTH
SNOW HILL
NORTH CAROLINA 28580

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
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7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Tom Weatherford — Senior Regulatory Consultant

Date: MARCH 30, 2001

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: Richard Pierce — Regulatory Specialist

Date: 03 April 01

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.

4-5-2001

White - EPA

★ U.S. GPO: 1995-386-820/20418

Paperwork Reduction Act Notice

The annual respondent burden for the Notice of Supplemental Distribution of a Registered Pesticide Product is estimated to average 15 minutes per response, including time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information. Send comments regarding this burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to Paperwork Reduction Project (OMB No. 2070-0044), Office of Management and Budget, Washington, DC 20503, Marked "Attention Desk Officer for EPA."

5546541 | 305
17

NOV 17 1998

John J. Lauber
Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

Subject: Deltamethrin 4% Collar
EPA Registration No. 68451-1
Amendment dated June 4, 1998

Dear Mr. Lauber:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you:

1. Make the following changes to your label:

a. Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable. Black-legged ticks is also acceptable. However, if a species name specific claim is made, then only *Ixodes scapularis* and/or *Ixodes pacificus* may be used in addition to the terms above. *Ixodes sp.* is not acceptable, and should be removed from the label and the above species names should replace it.

b. The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:

1) The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.

2) The data do not support the "kill" claim for mosquitoes. The range was 69% - 91.1%. The 91.1% mortality result was for one data point only. All other measurements of mortality were below 90%. This is less than the 95% required by Subdivision G Guidelines.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2. Submit two copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. I have also enclosed copies of the reviews for your records. If you have any questions about this letter, please contact Beth Edwards at (703) 305-5400.

Sincerely yours,

Beth Edwards

for George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosures

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

21 /OCTOBER/1998

MEMORANDUM

Subject: EPA Reg. No.: 68451-00001 Deltamethrin 4% Flea Collar
DP Barcode: D248074
Case No: 034680

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505C)

To: Beth Edwards, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant: Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, NJ 07059

FORMULATION FROM LABEL:

Active Ingredient(s):		% by wt.
097805 Deltamethrin		4.0
Inert Ingredient(s):		96.0
	Total:	100.%

ACTION REQUESTED: "Please review information submitted to support the revision of the First Aid Statement for the subject product to delete "induce vomiting."

BACKGROUND: The Registrant has submitted a letter proposing to revise the label concerning first aid statements for EPA Reg. No. 68451-00001 Deltamethrin 4% Collar. The revision would delete the instruction to "induce vomiting." The letter states as follows:

> "Since ingestion of even an entire flea collar does not appear to cause much of an acute toxicity hazard, except perhaps in very small children (and animals), it is our opinion that vomiting should not be induced as first aid treatment following collar ingestion due to the potential danger of aspiration (or other physical trauma) of the foreign material particularly if the collar has been bitten or chewed into smaller segments.
>
> In certain circumstances, particularly with ingestions by small children (and animals) for example, it may be necessary to retrieve the collar or segments of collar from the gastrointestinal tract using medical or pharmacological methods. Procedures such as this should be left up to the physician (veterinarian)."

RECOMMENDATIONS: We have reviewed the arguments and deem it appropriate to remove the statement "induce vomiting" from the label. The new label submitted contains the correct first aid statements for acute oral exposure.

8100

DP BARCODE: D248074

CASE: 034680 DATA PACKAGE RECORD DATE: 08/03/98
SUBMISSION: S546541 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
RANKING : 10 POINTS ()
CHEMICALS: 097805 Deltamethrin 4.0000%

ID#: 068451-00001 DELTAMETHRIN 4% COLLAR
COMPANY: 068451 HOECHST ROUSSEL VET S.A.
PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 217
PM TEAM REVIEWER: BETH EDWARDS 703-305-5400 ROOM: CM2 206
RECEIVED DATE: 07/09/98 DUE OUT DATE: 01/15/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 248074 EXPEDITE: N DATE SENT: 08/03/98 DATE RET.: / /
CHEMICAL: 097805 Deltamethrin
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: TRB	/ /	/ /
SECT: TOX	/ /	/ /
REVR :	/ /	/ /
CONTR:	10/20/98	/ /

ADMIN DUE DATE: ~~12/31/98~~ 11-30-98 emc
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review information submitted to support the revision of the First Aid Statement for the subject product to delete "induce vomiting."

MRID No. 445787-01

Thanks,
Beth Edwards
305-5400

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
248072	IB/PM03	08/03/98	12/31/98	Y	Y	Y

PRAT — can't assign to me Carrow
Not in label review
Not on TRB file
Not in catcher

EFFICACY STUDY REVIEW

by Kevin J. Sweeney, Entomologist - IB

To: Beth Edwards

Date: September 15, 1998

EPA Reg. or File No.: 68451-1

Product Name: Deltamethrin 4% Collar

Registrant: Hoechst Roussel Vet

PM: George LaRocca

Action: 305

Submission No. S546541

DP # : D248072

Chemical: deltamethrin 4%

Studies Submitted:

MRID # 44578702 Review of the Anti-feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies

MRID # 44578703 Initial "Kill" Activity of Deltamethrin 4% Collars Against *Ixodes scapularis* Nymphs using Treated Dog Hair as the Testing Substance

MRID # 44578704 Report of Laboratory Trials on the efficacy of Deltamethrin 4% Dog Collars for Control of Ticks - *Ixodes ricinus* and *Rhipicephalus sanguineus* in Dogs

MRID # 44602901 Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for control of Ticks - *Ixodes ricinus* and *Rhipicephalus sanguineus*.

MRID # 44578705 Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality, and Blood feeding of Adult *Aedes aegypti* Mosquitoes.

Comments:

The registrant wishes to add deer ticks and mosquitoes to the label.

Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable, black-legged ticks I also acceptable. However, if a species name specific claim is made - then only *Ixodes scapularis* and/or *Ixodes pacificus* may be used in addition to the terms above. *Ixodes sp.* is not acceptable, should be removed and the above species names should replace it.

The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:

1. The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.

2. The data do not support the "kill" claim for mosquitoes. The range was 69% - 91.1%. The 91.1% mortality result was for one data point only. All other measurements of mortality were below 90%. This is less than the 95% required by Subdivision G Guidelines.

I do not think we should entertain "aids in" claims for any repellent product or one meant to kill any public health pest feeding on a host.

DP BARCODE: D248072

CASE: 034680 DATA PACKAGE RECORD DATE: 08/03/98
SUBMISSION: S546541 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
RANKING : 10 POINTS ()
CHEMICALS: 097805 Deltamethrin 4.0000%

ID#: 068451-00001 DELTAMETHRIN 4% COLLAR
COMPANY: 068451 HOECHST ROUSSEL VET S.A.
PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 217
PM TEAM REVIEWER: BETH EDWARDS 703-305-5400 ROOM: CM2 206
RECEIVED DATE: 07/09/98 DUE OUT DATE: 01/15/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 248072 EXPEDITE: N DATE SENT: 08/03/98 DATE RET.: / /
CHEMICAL: 097805 Deltamethrin
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 12/31/98
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: IB	/ /	/ /	PROJ DATE: / /
SECT: PM03	/ /	/ /	
REVR :	/ /	/ /	
CONTR: Kevin Sweeney	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

attn: Efficacy

Please review studies submitted to support claims for deer ticks and mosquitoes.

MRID Nos. 445787-02; -03; -04; -05; and 446029-01.

Thanks,
Beth

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

JUL 23 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

HOECHST ROUSSEL VET S.A.
30 INDEPENDENCE BLVD.
P.O. BOX 4915
WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

446029-00

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: **Deltamethrin 4% Collar, EPA Reg. No. 68451-1**
Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Colar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber

John J. Lauber, Ph.D.
Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. **Name and address of submitter:**

Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

2. **Regulatory action in support of which this package is submitted:**

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3). (MRID No. 44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against *Ixodes scapularis* Nymphs using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3). (MRID No. 44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) in Dogs (EPA Guideline No.91-3). (MRID No. 44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3)
(MRID No. 44602901)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).
(MRID No.44578705)

5. Company Official: John J. Lauber, Ph.D. John J Lauber
Name Signature

6. Company Name: Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

7. Company Contact: John J. (Jack) Lauber, Ph.D.
Phone: 908/231-3426
FAX: 908/231-4462

Teresa, 7/10

The pages in German (25-182) were raw data. The registrant said this was not really necessary for review and so I have taken them out. They faxed me a replacement for page 1 to say "page 1 of 24" instead of "...182". Please send to SIG for MRID. Thanks,
Beth E.

Administrative Materials

JUN 18 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

HOECHST ROUSSEL VET S.A.
30 INDEPENDENCE BLVD.
P.O. BOX 4915
WARREN, NJ 07059

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Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [05] :

* An English translation is required for all work originally reported in other languages. Pgs. 25-182.

SIG - See me if you have any questions about this resubmission

Teresa
7/15

446029-00

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: **Deltamethrin 4% Collar, EPA Reg. No. 68451-1**
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- 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber

John J. Lauber, Ph.D.
Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. **Name and address of submitter:**

Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

2. **Regulatory action in support of which this package is submitted:**

Amended registration of Deltamethrin 4% Collar

3. **Transmittal date:**

June 1, 1998

4. **List of submitted studies:**

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3). (MRID No. 44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against *Ixodes scapularis* Nymphs using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3). (MRID No. 44578703)

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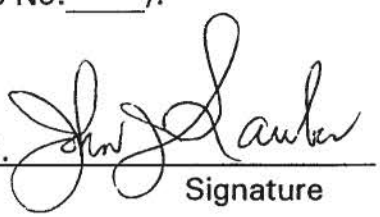
(MRID No.Reject (05))

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).
(MRID No.44578705)

5. **Company Official:** John J. Lauber, Ph.D. 
Name Signature

6. **Company Name:** Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

7. **Company Contact:** John J. (Jack) Lauber, Ph.D.
Phone: 908/231-3426
FAX: 908/231-4462

- 1st code in/out 305/10 Item 305-BE PR Eff JUN 18 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

HOECHST ROUSSEL VET S.A.
30 INDEPENDENCE BLVD.
P.O. BOX 4915
WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [05] :

* An English translation is required for all work originally reported in other languages. Pgs. 25-182.

445787-00

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: **Deltamethrin 4% Collar, EPA Reg. No. 68451-1**
Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber

John J. Lauber, Ph.D.
Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. **Name and address of submitter:**

Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

2. **Regulatory action in support of which this package is submitted:**

Amended registration of Deltamethrin 4% Collar

3. **Transmittal date:**

June 1, 1998

4. **List of submitted studies:**

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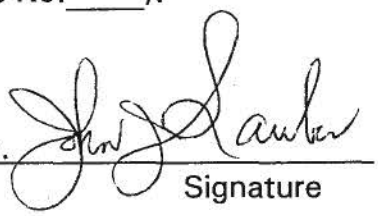
(MRID No.Reject (05)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).
(MRID No.44578705)

5. **Company Official:** John J. Lauber, Ph.D. 
Name Signature

6. **Company Name:** Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

7. **Company Contact:** John J. (Jack) Lauber, Ph.D.
Phone: 908/231-3426
FAX: 908/231-4462

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Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: **Deltamethrin 4% Collar, EPA Reg. No. 68451-1**
Amended Registration Application

Dear Mr. LaRocca:

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I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

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- 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber

John J. Lauber, Ph.D.
Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. **Name and address of submitter:**

Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

2. **Regulatory action in support of which this package is submitted:**

Amended registration of Deltamethrin 4% Collar

3. **Transmittal date:**

June 1, 1998

4. **List of submitted studies:**

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Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) in Dogs (EPA Guideline No.91-3). (MRID No.44578704)

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(MRID No.44578705)

5. **Company Official:** John J. Lauber, Ph.D. _____
Name Signature

6. **Company Name:** Hoechst Roussel Vet
P. O. Box 4915
Warren, N.J. 07059

7. **Company Contact:** John J. (Jack) Lauber, Ph.D.
Phone: 908/231-3426
FAX: 908/231-4462

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A)

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number: 254630 166132

Section I

1. Company/Product Number: 68451-1

2. EPA Product Manager: ~~G. LaRocca/13~~ 03
PM#: ~~13~~ 03

3. Proposed Classification: [ ] None [ ] Restricted

4. Company/Product (Name): Deltamethrin 4% Collar

5. Name and Address of Applicant *(Include ZIP Code)*:
Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

[X] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated _____.
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Label revision:
1. First Aid Statement - deleting "inducing vomiting"
2. Directions for Use - addition of claims for deer ticks and mosquitoes

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Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) of Retail Container
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
John J. Lauber Ph.D.	Manager, Product Registration	908-231-3426

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: John J. Lauber
3. Title: Manager, Product Registration
4. Typed Name: John J. Lauber
5. Date: June 4, 1998

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
254630

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ● Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ● Notification - Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

-VOID-

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ● ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
4. Typed Name	5. Date	

EPA Form 6570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
254630

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM#	☐ None ☐ Restricted
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☐ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification - Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

-VOID-

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
4. Typed Name	5. Date	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

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INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
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Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

NJF

Please read Instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

B

(A) **EPA** United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [X] Amendment
- [ ] Other

OPP Identifier Number: ~~254630~~ 166132

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
68451-~~1~~	G. ~~LaRocca/13~~ 03	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Deltamethrin 4% Collar	~~13~~ 03	

5. Name and Address of Applicant *(Include ZIP Code)*

Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section II

- [X] Amendment - Explain below
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label revision:
1. First Aid Statement - deleting "inducing vomiting"
2. Directions for Use - addition of claims for deer ticks and mosquitoes

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
John J. Lauber Ph.D.	Manager, Product Registration	908-231-3426

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
John J. Lauber	Manager, Product Registration	
4. Typed Name: John J. Lauber	5. Date: June 4, 1998	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [X] Amendment
- [ ] Other

OPP Identifier Number: ~~25463~~ 30 ~~166132~~

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
68451-1	~~G. LaRocca/13~~	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Deltamethrin 4% Collar	~~13~~ 03	

5. Name and Address of Applicant *(Include ZIP Code)*

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Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

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Product Name _____

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4. Typed Name	**5. Date**	
John J. Lauber	June 4, 1998	

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Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number: 166132

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
68451 - 1	G. LaRocca/13	☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
Deltamethrin 4% Collar	13	

5. Name and Address of Applicant *(Include ZIP Code)*

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Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

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EPA Reg. No. _____

Product Name _____

Section II

☐ Amendment - Explain below
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: *Use additional page(s) if necessary. (For section I and Section II.)*

NOTIFICATION: Additional Brand Name - Scalibor Dog Col

NOTIFICATION

JUN 20 1997

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) of Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
John J. Lauber Ph.D.	Manager, Product Registration	908-231-3426

Certification

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2. Signature	3. Title	6. Date Application Received (Stamped)
John J. Lauber	Manager, Product Registration	
4. Typed Name	5. Date	
John J. Lauber	May 23, 1997	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 17, 1997

Mr. John Lauber
Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
Warren, N.J. 07059

Dear Mr. Lauber:

Subject: Amendment - Efficacy Claims, Compliance with PRN 96-6
Deltamethrin 4% Dog Collar
EPA Reg. No. 68451-1
Your June 16, 1997 Submission

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE	10/17/97						

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

☆ U.S. GOVERNMENT PRINTING OFFICE 1995 - 619-457

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 1.1 oz

Hoechst Roussel Vet SA
102 route de Noisy
93235 Romainville, France

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL:
1-800-228-5635, ext. 132
FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2 ~~–3~~ weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*) and American dog tick (*Dermacentor variabilis*). This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar . Deltamethrin 4% Collar may be used in addition to a lead or constraint collar . Use only one Deltamethrin collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [X] Amendment
- [ ] Other

OPP Identifier Number: 254334 ~~166132~~

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
68451 -/	G. LaRocca/13	[ ] None [ ] Restricted
4. Company/Product (Name)	PM#	
Deltamethrin 4% Collar	13	

5. Name and Address of Applicant *(Include ZIP Code)*

Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. 360/525902

Product Name

EPA/OPP/OPPI MAY 19 P4:30

Section II

- [X] Amendment - Explain below
- [ ] Resubmission in response to Agency letter dated
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated
- [ ] "Me Too" Application.
- [ ] Other - explain below.

Explanation: *Use additional page(s) if necessary.* (For section I and Section II.)

The purpose of this submission is to revise the Deltmethrin 4% Collar label as required by PR 96-6, as well as to modify the Directions for Use and associated claims. Other label changes being proposed are the revision of the company name and insertion of a Disclaimer statement.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
*Certification must be submitted.	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
John J. Lauber Ph.D.	Manager, Product Registration	908-231-3426

Certification

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6. Date Application Received (Stamped)

2. Signature	3. Title
John J Lauber	Manager, Product Registration
4. Typed Name	5. Date
John J. Lauber	June 16, 1997

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

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United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

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Section I

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Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
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EPA Reg. No. _____

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Section II

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John J. Lauber	June 16, 1996

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United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [X] Amendment
- [ ] Other

OPP Identifier Number: 254334 ~~66132~~

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4. Typed Name: John J. Lauber	5. Date: June 16, 1997	

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EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
254334

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
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EPA Form 8570-1 (Rev. 6-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
254334

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM#	☐ None ☐ Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

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1-5. Self-explanatory.
6. EPA Use Only.

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber@bed1po1.hcc.com

June 16, 1997

Data Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

RECD EPA/OPP/DPD1
'97 JUN 19 P4:00

Subject: **Deltamethrin 4% Collar**
EPA Reg. No. 68451-1

Dear Mr. LaRocca:

Deltamethrin 4% Collar was registered by the Agency in 1996 for use on dogs for control of fleas and ticks. The purpose of this submission is to revise the Deltamethrin 4 % Collar label as required by PR Notice 96-6, as well as to modify the Directions for Use and associated claims. Other label changes being proposed are the revision of the company name and insertion of a Disclaimer statement.

By way of background, Roussel Uclaf Corporation (now AgrEvo Environmental Health (EPA Company No. 432) submitted an application to the U.S. EPA to register Deltamethrin 4% Collar, a product containing 4% deltamethrin. The pending registration was transferred to Roussel Uclaf, S.A., Division Santé Animale (EPA Company No. 68451) on March 23, 1995 On June 5, 1996, the U.S. EPA registered Deltamethrin 4% Collar, to Roussel Uclaf, S.A., Division Santé Animale. Subsequently, the company name of Roussel Uclaf, S.A., Division Santé Animale was changed to Hoechst Roussel Vet S.A.

At the time the Deltamethrin 4% Collar was registered, Hoechst-Roussel Agri-Vet Company (EPA Company No. 54382) was the agent of Roussel

Uclaf, S.A. The name of Hoechst-Roussel Agri-Vet Company was changed to Hoechst Roussel Vet. In regard to this amended registration of Deltamethrin 4% Collar, Hoechst Roussel Vet is acting as the agent of Hoechst Roussel Vet S.A.

Attached you will find 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text. In addition to this label showing the revisions, 5 copies of the label without crossed-out and underlined text are being submitted at this time.

Thank you in advance for processing this amended registration application and revised label If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber Ph.D.
Manager, Product Registration

Attachments
1. Amended Registration Application
2. Revised label showing deleted and new text
3. Revised label

cc
A. Ahlman w/ attachments
A. Benitz w/ attachments
R. Dodemaide w/ attachments
R. Muser w/ attachments

97 06 16c

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

- ~~✓ GUARANTEED WATERPROOF~~
- ~~✓ KILLS FLEAS FOR 11 MONTHS~~
- ~~✓KILLS TICKS FOR 7 MONTHS~~
- ~~✓ODORLESS~~
- ~~✓FITS DOGS WITH NECKS UP TO 21"~~
- ~~✓ GUARANTEED OR YOUR MONEY BACK~~
- ~~✓ WETTING WILL NOT IMPAIR THE COLLAR'S EFFECTIVENESS~~
- ~~✓MAY BE WORN WITH REGULAR COLLAR~~
- ~~✓PATENTED INSECTICIDE RELEASE TECHNOLOGY~~

ACTIVE INGREDIENT:	**Percentage by Weight**
Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

RECD EPA/OPP/OPD1
97 JUN 19 P4:02

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 1.1 oz

Hoechst Roussel Vet SA
~~Roussel Uclaf, S.A.~~
~~Division Santé Animale~~
102 route de Noisy
93235 Romainville, France

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

~~**GUARANTEED 11-Month Flea Killer**~~
~~**GUARANTEED 7-Month Tick Killer**~~

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks. ~~11-month flea-killing power (and 7-month protection against ticks). It's guaranteed!~~

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

~~**Do not use this product on cats.**~~ Do not use on puppies ~~less than 3 months of age~~ under 12 weeks. ~~This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using.~~ Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID ~~STATEMENT OF PRACTICAL TREATMENT~~

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL:
1-800-228-5635, ext. 132
FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be ~~are not~~ necessary ~~and therefore should not be used on dogs~~ while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, ~~that one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar~~ has been specially formulated using patented insecticide-release technology. ~~Because of the long duration of activity of the Deltamethrin 4% Collar,~~ Maximum effectiveness may not occur for 2 ~~–3~~ weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*) and American dog tick (*Dermacentor variabilis*). ~~Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem,~~ This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle ~~close to the buckle~~ and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. ~~Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear.~~ Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. ~~Replace when effectiveness diminishes. Deltamethrin 4%~~ Deltamethrin 4% Collar may be used in addition to ~~regular collar~~ a lead or constraint collar . Use only one Deltamethrin 4% ~~flea~~ collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

~~**NOTICE:** Buyer assumes all responsibility for safety and use not in accordance with directions.~~

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A.MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VETS.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

~~**ONE SIZE FITS ALL - TRIM TO SIZE**~~
~~This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.~~

Part No. XXXXX

Universal Product Code Number (Bar Code)

Dr. John J. Lauber
Hoechst Roussel Vet
Route 202-206 Bedm.
P.O. Box 2500
Somerville, NJ 08876-1258

MAR 17 1997

Dear Dr. Lauber

Subject: Condition of Registration- efficacy data
Deltamethrin 3% Collar
EPA Registration Number 68451-1
Deltamethrin 4% Collar
EPA Registration Number 68451-2
Your submission dated August 19, 1996

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the following reasons given below:

1. The data summaries (MRID 44190101) submitted to the Agency are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purpose of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with the lack of sufficient detail as to the manner in which the testing was conducted, as required by 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284.

A copy of the reviews are enclosed.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosures

EFFICACY REVIEW

DATE: IN 1-13-97 OUT 3- 6-97

FILE OR REG. NO. 68451-1

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED December 26, 1996

DATE OF SUBMISSION December 19, 1996

DATE SUBMISSION ACCEPTED

TYPE PRODUCT(S): (I,)D, H, F, N, R, S

DATA ACCESSION NO(S). 441901-01;D232552;S516908;Case#034680;AC:571

PRODUCT MGR. NO. 13-LaRocca/DeLuise

PRODUCT NAME(S) Deltamethrin 4% Collar

COMPANY NAME Hoechst Roussel Agri-Vet Company

SUBMISSION PURPOSE Provide performance data summaries in support of claims for control of fleas and ticks on dogs to establish new use for active chemical ingredient.

CHEMICAL & FORMULATION (s)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate 4.00% (impregnated material of unspecified bulk)

CONCLUSIONS & RECOMMENDATIONS The data summaries presented in EPA Accession (MRID) Number 441901-01, having been obtained from standard kennel tests presumably conducted according to a protocol that meets the requirements of § 95-30(b)(11)1. through 10. on pp. 280-4 and the standard of § 95-9(b)(2)(i) on p. 264 of the Product Performance Guidelines, are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purposes of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with lack of sufficient detail as to the manner in which testing was conducted, as required by § 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284. While Reference 1 comes closer to meeting these requirements, References 2 and 3 are only summary and abstract, respectively. References 4 through 6 are for kennel tests conducted in Europe, and while Reference 4 (to be continued)

actually gives more details as to these requirements than do the latter two reports from the U. S., it fails to identify all the formulations in the test as to active ingredient as required by § 95-30(b)2.5; References 5 and 6 are nothing more than conclusions and lack sufficient detail in many of the categories previously mentioned above. Furthermore, since the submission was not accompanied by either labeling or CSF, it is not possible to relate the conclusions and results of any of these references to the support of specific claims of duration of satisfactory control or range of flea and tick species against which the collar is found effective. Mention is made at the end of Reference 1 of original data found in the Appendix, pp. A41-A124, and of quality assurance unit inspections and the final report following the Appendix as pp. QUA1-QUA9. The submission of this information along with specific information meeting above requirements with respect to References 2 through 6 is necessary for proper review of the effectiveness of the collar, along with labeling as to the claims which these data are believed to satisfactorily support.

OBJ Vern L. McFarland, IRB

Hoechst Roussel Vet

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

441901-OD

August 19, 1996

Mr. George T. LaRocca
Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

Subject: **Deltamethrin 3 and 4% Collars**
EPA Registration Nos. 68451-1 and 2
Notice of Registration Dated June 5, 1996

As a condition of the registrations of the Deltamethrin 3 and 4% Collars, we committed to submit to the Agency within three months of the date of the Registration Notice, a summary of efficacy data demonstrating control of fleas and ticks. Attached you will find three copies of the report: "Deltamethrin Dog Collars - Efficacy Studies". In this report, the results of several efficacy studies with the 3 and 4% collars are presented.

44190101

Sincerely yours,

John J. Lauber

John J. Lauber, Ph.D.
Manager, Product Registration
Agent for Roussel Uclaf, S.A., Division Santé Animale

Attachment: 3 copies of the report "Deltamethrin Dog Collars - Efficacy Studies".

Hoechst Roussel Vet

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

December 19, 1996

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Dear Sir/Madam:

Subject: **Deltamethrin 3 and 4% Collars**
EPA Registration Nos. 68451-1 and 2
Hoechst Roussel Vet submission dated August 19, 1996
EPA Report of Analysis for Compliance with 86-5 dated September 4, 1996

On December 17, I received the "Report of Analysis for Compliance with PR Notice 86-5"(copy enclosed). The notice was dated September 4, 1996. I don't know why the notice was delayed in reaching me.

The notice indicated that our statement of no data confidentiality claims is contradicted by the markings on the first page of Reference 4. I have corrected this and am enclosing 3 copies of this corrected page. Please remove the old page from the copies previously submitted and substitute the new page.

Thank you in advance for your help.

Sincerely yours,

John J. Lauber Ph.D.
Manager, Product Registration

Enclosures
961218b

166550 6323
17/

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
68451-1	5 JUN 1996

Term of Issuance: Unconditional

Name of Pesticide Product: Deltamethrin 4% Collar

Name and Address of Registrant (include ZIP Code):

Hoechst-Roussel Agri-Vet Company
Route 202-206 Bedm. 1
PO Box 2500
Somerville, NJ 08876-1258

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B).

1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1".

2. We note that in your May 14, 1996 letter you agreed to submit efficacy data supporting label claims within 3 months of the date of this notice.

3. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

CONCURRENCES							
SYMBOL	Signature of Approving Official:				Date:		
SURNAME							
DATE	EPA Form 8570-6						

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_x_ Registration
____ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
68451-1	

Term of Issuance:
Unconditional

Name of Pesticide Product:
Deltamethrin 4% Collar

Name and Address of Registrant (include ZIP Code):
Hoechst-Roussel Agri-Vet Company
Route 202-206 Bedm. 1
PO Box 2500
Somerville, NJ 08876-1258

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B).

1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1".

2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Signature of Approving Official:	Date:

EPA Form 8570-6

Helen

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

- ✓ **GUARANTEED WATERPROOF**
- ✓ **KILLS FLEAS FOR 11 MONTHS**
- ✓ **KILLS TICKS FOR 7 MONTHS**
- ✓ **ODORLESS**
- ✓ **FITS DOGS WITH NECKS UP TO 21"**
- ✓ **GUARANTEED OR YOUR MONEY BACK**
- ✓ **WETTING WILL NOT IMPAIR THE COLLAR'S EFFECTIVENESS**
- ✓ **MAY BE WORN WITH REGULAR COLLAR**
- ✓ **PATENTED INSECTICIDE RELEASE TECHNOLOGY**

ACTIVE INGREDIENT:	**Percentage by Weight**
Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar
NET WT. 1.1 oz

Roussel Uclaf, S.A.
Division Santé Animale
102 route de Noisy
93235 Romainville, France

ACCEPTED
with COMMENTS
in EPA Letter Dated

16 JUN 1996

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.
68451-1

May 14, 1996

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11-Month Flea Killer
GUARANTEED 7-Month Tick Killer

Deltamethrin 4% Collar provides full season, 11-month flea-killing power (and 7-month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. **Do not use this product on cats.** Do not use on puppies less than 3 months of age.

This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2 - 3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*) and American dog tick (*Dermacentor variabilis*). Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL - TRIM TO SIZE
This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

May 14, 1996

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

May 14, 1996

4%

deltamethrin

dog collar

Mr. George T. LaRocca
Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

Subject: Registration Application
Deltamethrin 4% Collar
EPA File Symbol 68451-R
Your Letter Dated May 2, 1996

You indicated in your letter that the subject product is acceptable for registration provided that we agree in writing to the following:

1.Submit a summary of efficacy data demonstrating control of fleas and ticks that are consistent with labeling claims. This information to be submitted to the Agency within 3 months of the date of the registration notice

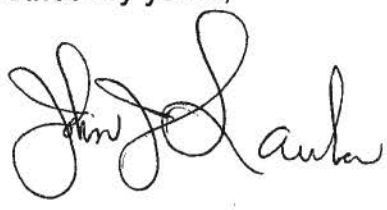
2. *Make labeling changes*

We agree to supply to the Agency a summary of efficacy data demonstrating control of fleas and ticks within 3 months of the date on the Notice of Registration.

I am enclosing three copies of final printed labeling in which I have incorporated all the changes that you requested.

I believe all is in order and that the Notice of Registration can be issued. Thank you in advance for receipt of the Notice.

Sincerely yours,



John J. Lauber, Ph.D.
Manager, Biologics & Pesticide Product Registration
Agent for Roussel Uclaf, S.A., Division Santé Animale

Enclosure

cc by e-mail
L. Ahlman
A. Benitz
C. Chieze
R. Dodemaide
A. Donoghue
C. Focheux
D. Frey
PY Kravtchenko
R. Muser
JP Scheid

96 05 08b

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

166 5494967
166 5494960
16/1

02 MAY 1996

Mr. Jack Lauber
Roussel Uclaf
Hoechst-roussel Agri-Vet Co.
Route 202-2026
PO Box 2500, Bedm. 31
Somerville, NJ 08876-1258

Dear Mr. Lauber:

Subject: Registration Application
Deltamethrin 4% Collar
EPA File Symbol 68451-R
Your Letter Dated August 11, 1993

The product referenced above will be acceptable for registration under FIFRA sec. 3(c)(7)(A) and (B) provided that you agree in writing to:

1. Submit a summary of your efficacy data demonstrating control of fleas and ticks that are consistent with labeling claims. We request this information be submitted to the Agency within 3 months of the date of this registration notice.

And make the following labeling changes:

2. Revise your Statement of Practical Treatment as follows: IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF ON EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

   Refer to your copy of the May 16, 1995 Precautionary Review Section review for complete information on your product's acute toxicity profile.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

3. Revise the heading so it reads Hazards to Humans and Domestic Animals. Also, revise the statements so that they read "Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Do not use this product on cats (note: this sentence should appear in **bold**). Do not use on puppies less than 3 months of age.

4. Revise the statements regarding sick or convalescing dogs to read as follows: "This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using."

5. Delete the statement "Initial use of collar is to be in conjunction with dip or dust." Your product should not depend on other products for efficacy. If this collar is part of a flea control program you should list specific (active ingredient) products to be used. Depending on the type of product(s) chosen and the rate of application we may require additional domestic animal safety and/or efficacy data.

6. Delete "..and deer tick (Ixodes scapularis) which may carry Lyme disease." This is a public health claim which requires the submission of supportive efficacy data.

7. Delete the claims "new molecule - first collar formulated with a pyrethroid" and "one of the longest lasting flea and tick killers...etc." There are other pyrethroid collars registered. Also words or phrases implying that a product possesses unique characteristics because of its composition are not acceptable. You may use the word new or new formulation for a period of six months following the notice of registration.

8. Under the signal word we recommend revise "Keep out of the reach of children" to "Do not let children play with this collar."

9. Singularize the term Active Ingredients. Your product contains only one active ingredient.

10. Delete the asterisk and have the chemical name follow the common name in the ingredient statement. Deltamethrin was registered in the U. S. two years ago and is not considered a commonly recognized name in the U. S.

You will submit three copies of your final printed labeling before you release the product for shipment.

The "Notice of Registration" will be issued when you have agreed in writing to the conditions stated above and submitted corrected labels.

THIS LETTER DOES NOT CONSTITUTE REGISTRATION, AND THE PRODUCT MAY NOT BE LAWFULLY MARKETED UNTIL IT IS REGISTERED.

Please respond within 75 days from the date of this letter stating your intentions to comply with the information/data requests cited above. If no resubmission is received during the 75-day period, the application will be administratively withdrawn.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

Resubmission - 5/14

* 8-1-9

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258
Telex 833-449 Cable Hoechstus, Somerville, NJ

Telephone (908) 231-3426 Fax (908) 231-4462

August 22, 1995

Mr. George T. LaRocca (PM 13)
Office of Pesticide Programs (H7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: **Deltamethrin 4% Dog Collar**
EPA File Symbol 68451-R (previously EPA File Symbol 432-TTO)

Dear Mr. LaRocca:

As the authorized representative and principal contact of Roussel Uclaf, S.A., Division Santé Animale, I am responding to the questions raised in a Product Chemistry Review concerning the Deltamethrin 4% Dog Collar.

By way of background, on August 11, 1993, Roussel Uclaf Corporation (now AgrEvo Environmental Health) submitted a Registration Application (plus supporting information) for the registration of Deltamethrin 4% Dog Collar. The pending registration was assigned EPA File Symbol 432-TTO. On March 23, 1995, the pending registration was transferred to Roussel Uclaf, S.A., Division Santé Animale. The pending registration was assigned EPA File Symbol 68451-R. On April 13, 1995, Mr. John Hebert of your staff provided me with the Product Chemistry Review dated December 28, 1993.

The Product Chemistry Review raised the following requirements:

1. Revise the label ingredient statement

2. Revise the Confidential Statement of Formula by correcting the CAS # for deltamethrin

Product ingredient source information may be entitled to confidential treatment

3. Revise the manufacturing process relative to temperature (Fahrenheit or Centigrade).

4. Provide information concerning Corrosion Characteristics, Storage Stability, and Flammability

5. Provide additional information concerning three inert ingredients previously not approved for use in dog collars

Our response to these requirements is as follows;

1. Revision of the Label Ingredient Statement

Attached you will find a revised label which positions the ingredient statement as specified in the product chemistry review. The name and address of the registrant was also revised because of the transfer of the pending registration.

2. Revision of the Confidential Statement of Formula

While not stated in the product chemistry review, the Confidential Statement of Formula needs to be revised to reflect that the Deltamethrin Technical used in making the Deltamethrin 4% Dog Collar is [redacted] active as indicated on the Confidential Statement of Formula dated August 11, 1993. Attached you will find a revised Confidential Statement of Formula revised to reflect the [redacted] In addition, I have corrected the CAS # for deltamethrin and revised the amounts in Sections 13 and 14 to reflect the very slight change in introducing a Deltamethrin Technical of lower concentration, and its slight effect on the concentration of solvent used in making the product. Also, I have revised Sections 1, 2, and 6 to reflect the new registrant Roussel Uclaf, S.A., Division Santé Animale.

3. Manufacturing Process Revision

On page 6, CONFIDENTIAL ATTACHMENT, Volume 1 of the August 11, 1993 submission concerning the Manufacturing Process, all temperatures shown should be ° F. A corrected page is attached.

4. Corrosion Characteristics, Storage Stability, and Flammability

With our submission dated August 21, 1995, we submitted a report which will satisfy the Product Chemistry requirements for Corrosion Characteristics and Storage Stability.

Concerning flammability, the Agency states in its Guidelines Ref. 63-15 (40 CFR 158.190) that flammability data is "required if the product contains combustible liquids". Deltamethrin 4% Dog Collar does not contain any liquid combustible ingredients. It is not flammable and consequently, a flammability test was not performed.

5. Inert Ingredients Not Approved for Use in Dog Collars

Information concerning the three inert ingredients previously not approved for use in dog collars has been submitted to the Agency under separate cover.

If you have any questions or require additional information, please do not hesitate to contact me. Thank you in advance for your help concerning the registration of Deltamethrin 4% Dog Collar.

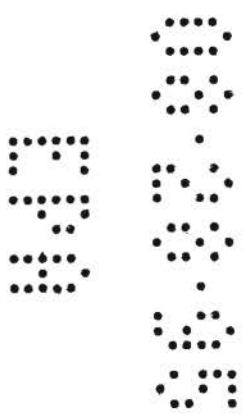
Sincerely yours,

John J. Lauber Ph.D.
Manager, Product Registration

Attachments
Revised label (5 copies), revised CSF, revised p.6 of CONFIDENTIAL ATTACHMENT pertaining to manufacturing,

cc
L. Ahlman
C. Chieze
A. R. Donoghue
D. Frey
P.-Y. Kravtchenko
R. K. Muser
L. Poly
J. P. Scheid
M. Trausinger

/95 08 17c



DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
✓	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA & TICK KILLERS AVAILABLE FOR USE ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENT:	Percent by Weight
Deltamethrin*	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: **Keep out of reach of children**

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar
NET WT. 1.1 oz

EPA Reg. No. 68451-

EPA Est. No.

Aug. 22, 1995

Roussel Uclaf, S.A.
Division Santé Animale
102 route de Noisy
93235 Romainville, France

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer
GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
CAUTION:
Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

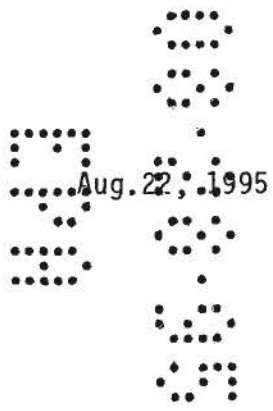
DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE
This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 16 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Id# 000432-TTI. Deltamethrin: Review of a domestic animal safety study with the product "Deltamethrin 3% Collar".

TOX CHEM No.: 463B
PC No.: 097805
Barcode No.: D194602
Submission No.: S446520

FROM: John Doherty
Section IV, Toxicology Branch I
Health Effects Division (7509C)

TO: George LaRocca/John Hebert
Product Manager #13
Registration Division (7505C)

THROUGH: Marion Copley, DVM, Section Head
Section IV, Toxicology Branch I
Health Effects Division (7509C)

Marion Copley 11/15/93

I. CONCLUSION

The domestic animal safety study with the product Deltamethrin 3% Collar was reviewed and determined to be ACCEPTABLE. No reactions to treatment were noted when one collar (4% active ingredient worn for six months), four collars (3% active ingredient worn for three months, or 4% active ingredient worn for six months) were worn.

The product has been demonstrated to be safe for adult dogs. If the registrant wishes to register the product for use on dogs less then 3 months of age an additional study using puppies of defined age will have to be presented.

II. Action Requested

The Roussel Uclaf Company (refer to letter from Sharon M. Johnson dated July 9, 1993) has submitted a domestic animal safety study (MRID No.: 428890-06) with dogs to support the registration of the product Deltamethrin 3% Collar. The study was reviewed and the following comments apply.

III. Toxicology Branch Comments

1. The study was determined to be ACCEPTABLE and to demonstrate the safety of the product to adult (see item 2 below) dogs. The study demonstrated that there were no effects of wearing 3 or 4 collars equivalent to 3 or 4 times the recommended usage rate for up to six months. Refer to the DER attached.

2. The age of the test dogs was not specified in the study report. Therefore, the product is considered to have been demonstrated to be safe for use on adult dogs (greater than 3 months of age). The product label should thus include in the precautionary statement for use on dogs of greater than 3 months of age only. Or do not use on puppies less than 3 months of age. [Note: This precautionary statment is already included on the draft label dated July 20, 1993.]

If the registrant wants to use the product on puppies less than 3 months of age, the registrant will have to provide the exact ages of the dogs used in the existing study and demonstrate that treatment was initiated at a specified age less than 3 months.

Alternatively, the registrant will have to submit a second study in which the treated puppies are of a defined age. For example, if one month old puppies are treated, and the study demonstrates the 3 fold safety factor in which no reactions are noted, the product label can be amended to include for use of puppies greater than one month of age. If this study is conducted, the puppies should not have to treated for more than two weeks and the ChE and AChE assays should not have to be included.

IV. Studies Reviewed

Study Identification	Material	MRID No.:	Results	Classification
86-1. Domestic animal safety study-dogs. Hazleton # HWA 2623-103. April 11, 1993	3% and 4% deltamethrin containing collars from lots 1103 (3%) and 1104 (4%).	428890-06	No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months). Mongrel purpose bred dogs. Control (4 collars without delta-methrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.	ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

Reviewed by: John Doherty 11/15/93
Section IV, Toxicology Branch I (7509C)
Secondary reviewer: Marion Copley, DVM 11/12/93
Section IV, Toxicology Branch I (7509C)

DATA EVALUATION REPORT

STUDY TYPE: 86-1. Domestic animal safety study (6 month-dogs)

MRID NO.: 428890-06. TOX. CHEM. NO.: 463B
PC No.: 097805

TEST MATERIAL: 3% (from lot No.: 1103) and 4% (from lot 1104) deltamethrin fortified dog collars.

STUDY NUMBER(S): HWA 2623-103 and RBT No.: 91-135.

SPONSOR: Roussel Bio Corporation, Lincoln Park, New Jersey

TESTING FACILITY: Hazleton Washington, Inc.

TITLE OF REPORT: "6-Month Deltamethrin Flea and Tick Collar Safety Study in Dogs"

AUTHOR(S): Dan W. Dalgard, D.V.M.

REPORT ISSUED: April 11, 1993

STUDY DATES (in life): Initiation: November 27, 1991, Termination June 29, 1992.

CONCLUSIONS:

No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months).

Mongrel purpose bred dogs. Control (4 collars without deltamethrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.

Classification: ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

Quality Assurance Statement: Provided.
Good Laboratory Practice Statement: Provided.

All dogs survived the experiment and no treatment related findings were noted.

2. Body weight and feed consumption.

Body weight and feed consumption were reportedly assessed weekly. The study author maintains that there were no compound related effects on these parameters.

TB-I considers that the body weight and feed consumption data showed variations for which interpretation was confounded by the fact that the dogs were mongrels and of different sizes and there were only four dogs/sex/treatment group. Inspection of the growth curve for females (refer to Figure 3, photocopied from the study report attached) supports the conclusion of the study author. The male group wearing only one collar had a higher rate of growth than the other dogs. The report, however, asserts that this is related to the dogs being mixed and mongrels. Since the dogs wearing four collars (with either 3 or 4% deltamethrin) did not also show indications of similar increased weight gain, TB-I concurs that the weight gain pattern for the group wearing only one collar was not affected by the presence of the deltamethrin in the collar.

There also appeared to be an increase in feed consumption in the dogs (both sexes) wearing 4 collars with 4% deltamethrin in the later weeks of the study (refer to Figure 3 photocopied from the study report attached). TB-I does not consider that the apparent increase is conclusively related to treatment.

3. Clinical Hematology and Biochemistry

Samples of blood were taken from the jugular vein from fasted dogs on days -7, -6, -3, 2, 4, 8, 15, 22, 29, 54 and 89 and 180. for plasma ChE and RBC AChE. Blood samples for days -13, 25, 51 and 86 and 177 were also taken for hematology and serum chemistry.

A. Hematology. The following hematology parameters were reportedly investigated.

cell morphology
corrected leukocyte count
erythrocyte count
erythrocyte sedimentation rate
hematocrit
hemoglobin
leucocyte count
leucocyte differential
platelet

No consistent compound related effects were noted on any of these parameters.

REVIEW

Experimental Constants:

Test Material: Deltamethrin impregnated dog collars containing 3% (from lot #1103) or 4% (from lot #1104) and placebo collars without deltamethrin (lot # 110C) obtained from the Roussel Uclaf Company.

Test System: Purpose bred mongrel dogs with both short and long hair were obtained from the Hazleton Research Products, Inc. Cumberland, Virginia. The exact age of the dogs at initiation of dosing (age of application of the collars) was not referenced in the report.

Basic Experimental Design

Four groups of 4/sex dogs which consisted of a control (placebo collar), low dose (usage rate or one collar of 4% deltamethrin, actually slightly greater than the usage rate of a 3% collar), mid dose (4 collars of 3% deltamethrin) and high dose (4 collars of 4% deltamethrin). The dogs were scheduled to wear their collars for six months. After three months, the mid dose group was terminated because there were no reactions noted in any group. The control, low and high dose groups continued for the scheduled six months.

Analytical Chemistry

1. Release rates of deltamethrin from the collars. Sections of the 3% and 4% collars were removed and analyzed for deltamethrin at pretest, at three and six months to determine the rate of release from the matrix. The Analytical report is in Appendix 11. In summary the analytical data were shown to have release rates 120 ug/collar/day for the 3% collar at the 3 month interval. The 4% collars were shown to have release rates of 40 and 251 ug/collar/day at the 3 and 6 month intervals.

2. Blood levels of deltamethrin. The blood was sampled from the dogs wearing only one collar on days 25, 51, 86 and 177 and analyzed for deltamethrin content. The limit of assay was said to be 5 ng/ml. No detectable deltamethrin was evident at days 25, 51 and 86. Although some evidence of < 5 ng/ml was noted for three dogs at day 177, the study report did not consider these readings actual (referring to them as incidental). TB-I concurs and does not consider that wearing a single collar resulted in significant levels of deltamethrin in the blood.

Assessments and Results

1. Survival and clinical signs.

The dogs were reportedly examined twice daily for mortality and once daily for behavioral reactions. In addition, a staff veterinarian examined the dogs on days 1, 8, 26, 88 and 179 (in addition to two pretreatment examinations) for dermatological and clinical evaluations including heart and respiratory rate and body temperature recordings.

B. Serum Chemistry

alanine aminotransferase (ALT
albumin
albumin/globulin ratio
alkaline phosphatase
aspartate aminotransferase
blood urea nitrogen
calcium
chloride
creatine kinase
creatinine
globulin
glucose
inorganic phosphorous
potassium
sodium
total bilirubin
total protein
RBC AChE
Plasma ChE

No consistent compound related effects were noted on any of these parameters.

There were some instances on increased RBC AChE (including in the preapplication period) and plasma ChE. Increases in the activity of these enzymes is not a recognized toxicity response. Since there was no inhibition of these enzymes and the increases were not related to the quantity of the collars worn, it is concluded that the treatment did not affect these enzymes. Moreover, ChE and AChE are not recognized as being inhibited by pyrethroids such as deltamethrin.

No necropsy was performed and is not considered necessary.

CONCLUSION (Study). The study is considered ACCEPTABLE. No additional domestic animal safety studies are required at this time. The study supports the following "one liner":

No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months).

Mongrel purpose bred dogs. Control (4 collars without deltamethrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.

FIGURE 3 – MEAN FOOD CONSUMPTION

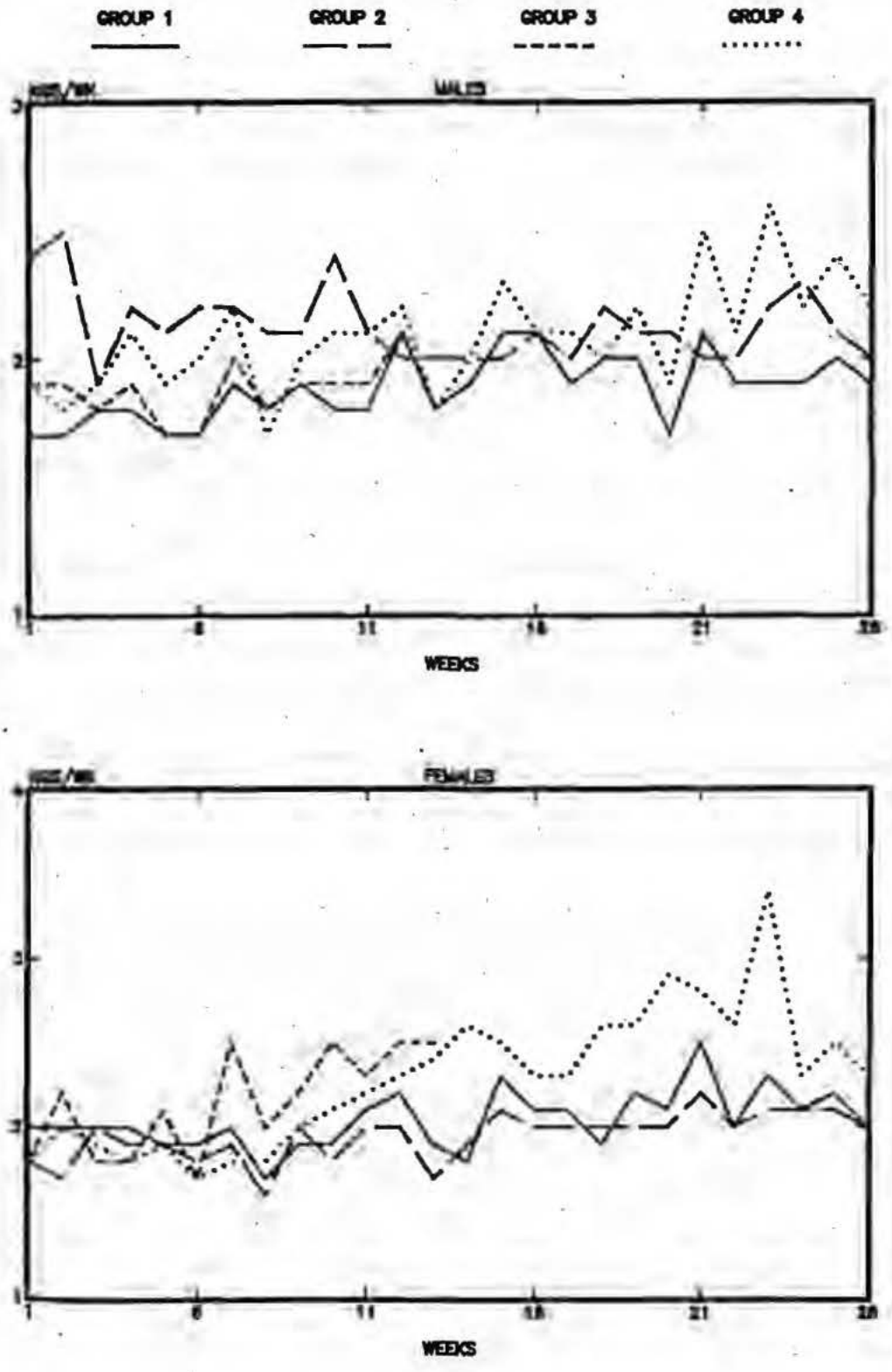
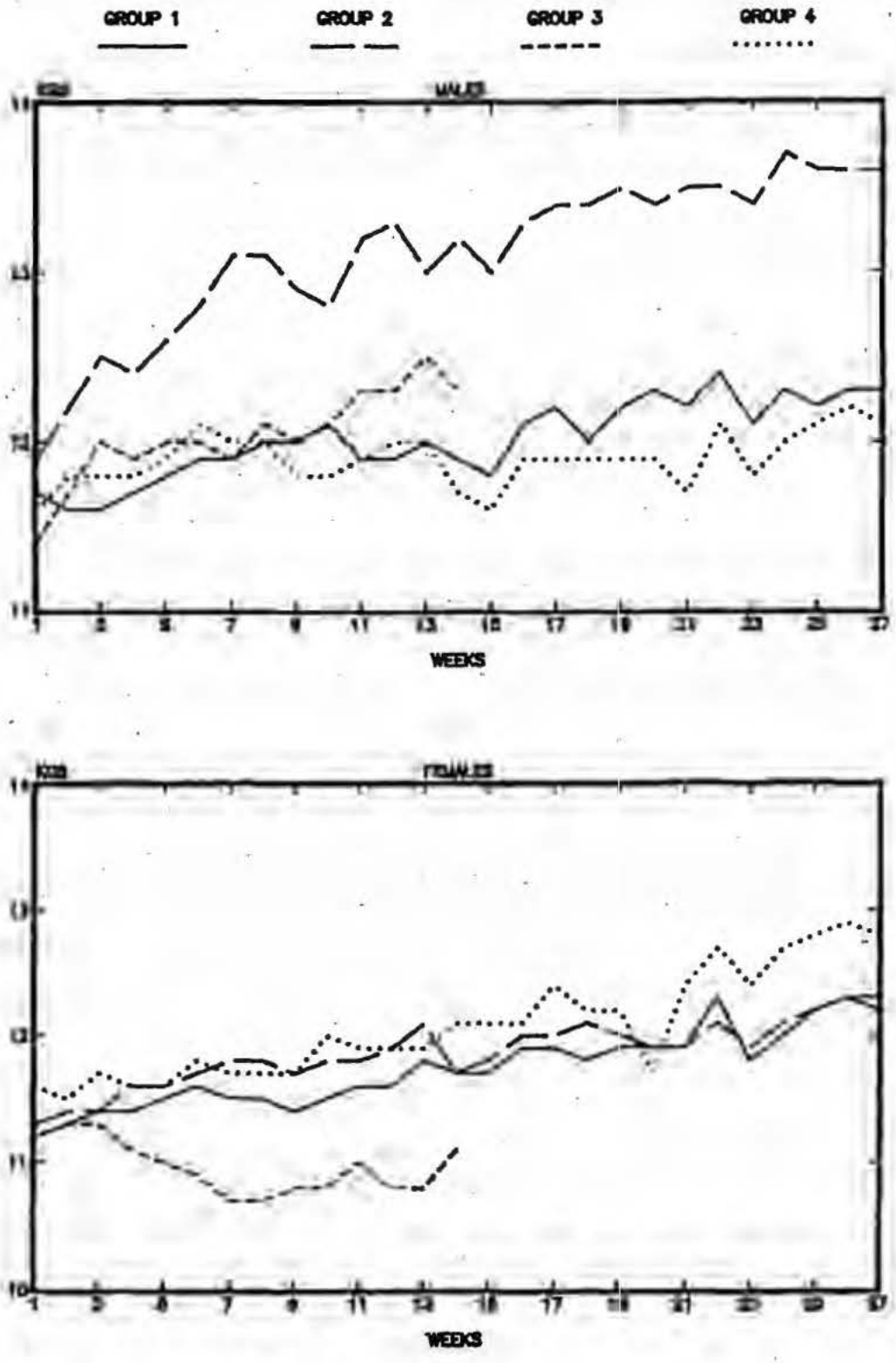


FIGURE 2 – MEAN BODY WEIGHTS



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPTIONAL FORM 99 (7-90) 6-23-95

FAX TRANSMITTAL # of pages ▶ 9

To Jack Lauleer	From John Hebert
Dept./Agency Roussel	Phone # 703 305 5419
Fax # 908 231 3426	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA File Symbols: 432-TTI / 432-TTO

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP 5-16-95

To: G. LaRocca, PM-13 / J. Hebert
Registration Division (7505C)

PM-13
George LaRocca
908-231-4462

Applicant: Roussel-Uclaf Corp.
95 Chestnut Ridge Road
Montvale, NJ 07645

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): Deltamethrin	4.0
Inert Ingredient(s):	96.0
Total:	100%

BACKGROUND

Roussel-Uclaf Corporation submitted acute oral, acute dermal, eye irritation, dermal irritation and dermal sensitization studies, as well as an acute inhalation waiver request for review. The studies were performed with the Deltamethrin 4% Collar (EPA File Symbol 432-TTO); the registrant has requested that these studies also support registration of the Deltamethrin 3% Collar (EPA File Symbol 432-TTI). Both products are insecticidal dog collars containing deltamethrin as the only active ingredient.

The performing laboratory is Stillmeadow, Inc., and the assigned MRID numbers are 428890-01 through 428890-05.

RECOMMENDATIONS

1. Acute Oral; Category III / Acceptable

2. Acute Dermal; Category III / Acceptable

An impermeable material, such as plastic, is recommended for semi-occlusion in dermal toxicity studies.

3. Acute Inhalation; Waiver Accepted

PRS does not believe that this product poses a significant inhalation hazard.

4. Eye Irritation; Category III / Acceptable

5. Dermal Irritation; Category IV / Acceptable

6. Dermal Sensitization; Non-sensitizer / Acceptable

The study report failed to specify that the concentration selected for induction and challenge was the highest achievable concentration after moistening.

More detailed positive control data was obtained from the performing laboratory (attached). Although the positive control study employed the same concentration for induction and challenge, the data does demonstrate a sensitizing response.

LABELING

1. The recommended signal word is "caution."

2. The recommended statements of practical treatment are as follows:

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

3. The recommended precautionary statements are as follows:

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

4. The signal word should appear on a separate line just below the child hazard warning ("Keep out of reach...").

4

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (81-1)

Product Manager:13 **Reviewer:**M. Perry
MRID No.:428890-01 **Report Date:**3/11/92
Testing Facility: Stillmeadow **Report No.:**8668-92
Author(s):J. Kuhn
Species: Rat
Age: Young adult
Weight:175-243 g
Source: Harlan SD
Test Material: Deltamethrin 4% Collar (reduced)
Quality Assurance (40 CFR 160.12): Present

Conclusion:

1. LD_{50} (mg/kg): **Males=** 4218 mg/kg
Females= 3600 mg/kg
Combined= 3920 mg/kg
2. **The estimated LD_{50} is 3920 mg/kg.**
3. **Tox. Category:**III **Classification:**Acceptable

Deviations from 81-1: None
Results:

Dosage mg/kg	(Number Killed/Number Tested)		
	Males	Females	Combined
2500	0/5	0/5	0/10
3500	1/5	2/5	3/10
5050	4/5	5/5	9/10

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (81-2)

Product Manager:13 **Reviewer:**M. Perry
MRID No.:428890-02 **Report Date:**2/21/92
Testing Laboratory: Stillmeadow **Report No.:**8669-92
Author(s):J. Kuhn
Species: Rabbit
Weight:2.0-2.6 kg
Source: Ray Nichols
Test Material: Deltamethrin 4% Collar (reduced)
Quality Assurance (40 CFR 160.12): Present

Summary:

1. LC_{50} **(mg/kg):** **Males=** --
Females= --
Combined 2020 mg/kg

2. **The estimated** LD_{50} **is** greater than 2020 mg/kg.

3. **Tox. Category:**III **Classification:**Acceptable

Deviation From 81-2: See recommendations

Results:

Reported Mortality

DOSAGE mg/kg	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2020	0/5	0/5	0/10

DATA REVIEW FOR SKIN IRRITATION TESTING (81-5)

Product Manager:13
MRID No.:428890-04
Testing Laboratory: Stillmeadow
Author(s):J. Kuhn
Species: Rabbit
Age: Young adult
Sex:3 male, 3 female
Weight:--
Dosage:0.5 g
Test Material: Deltamethrin 4% Collar (reduced)
Quality Assurance (40 CFR 160.12): Present

Reviewer:M. Perry
Report Date:2/11/92
Report No.:8671-92

Summary:

1. **The Primary Irritation Index**= --

2. **Toxicity Category:**IV
3. **Classification:**Acceptable

Deviations From 81-5: None

Results: No irritation was reported in any animal during the observation period.

DATA REVIEW FOR SKIN SENSITIZATION TESTING (81-6)

Product Manager:13
MRID No.:428890-05
Testing Laboratory: Stillmeadow
Author(s):J. Kuhn
Species: Guinea pig
Weight:280-370 g
Source: Harlan SD
Test Material: Deltamethrin 4% Collar (reduced)
Positive Control Material:DNCB
Quality Assurance (40 CFR 160.12): Present

Reviewer:M. Perry
Report Date:3/16/92
Report No.:8672-92

Method: Buehler

Summary:

1. **According to the study results, this Product is not a dermal sensitizer.**

2. **Classification:**Acceptable

Deviation From 81-6: See recommendations.

Results: No irritancy response was reported in the test or naive control animals at challenge.

ACUTE TOX ONE-LINER

1. PC CODE: 097805

2. CURRENT DATE: 5/12/95

3. TEST MATERIAL: Deltamethrin 4%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
81-1, Rat, Still-eadow, 8668-92, 3/11/92	428890-01	LD50 = 3920 mg/kg	III	A
81-2, Rabbit, Still-meadow, 8669-92, 2/21/92	428890-02	LD50 2020 mg/kg	III	A
81-4, Rabbit, Still-meadow, 8670-92, 2/12/92	428890-03	Irritation cleared by 72 hrs.	III	A
81-5, Rabbit, Still-meadow, 8671-92, 2/11/92	428890-04	No irritation reported	IV	A
81-6, Guinea pig, Stillmeadow, 8672-92, 3/16/92	428890-05	Non-sensitizer	---	A

Core Grade Key:

A = Acceptable
S = Supplementary
U = Unacceptable

.C .

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (81-4)

Product Manager: 13
MRID No.: 428890-03
Testing Laboratory: Stillmeadow
Author(s): J. Kuhn
Species: Rabbit
Sex: 3 female, 3 male
Weight: --
Source: Ray Nichols
Dosage: 50.4 mg
Test Material: Deltamethrin 4% Collar (reduced)
Quality Assurance (40 CFR 160.12): Present

Reviewer: M. Perry
Report Date: 2/12/92
Report No.: 8670-92

Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Deviations From 81-4: None

Results: All "positive" scores cleared between 24 and 72 hours post dosing.

-10-

DELTAMETHRIN 3% COLLAR

FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 6 MONTHS
✓	KILLS TICKS FOR 4 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA & TICK KILLERS AVAILABLE FOR USE ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	3.00%
Inert Ingredients	97.00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: **Keep out of reach of children**

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar
NET WT. 1.1 oz

EPA REG. NO. 432- EPA EST. NO. CODE

Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

DELTAMETHRIN 3% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 6 Month Flea Killer
GUARANTEED 4 Month Tick Killer

Deltamethrin 3% Collar provides full season, 6 month flea killing power (and 4 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
CAUTION:
Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Deltamethrin 3% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 3% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 3% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 4 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 3% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE
This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

9082314462

REG. NO: **00432-TTO** Submission: **S452561**

FILE SYMBOL: **D196505**

PRODUCT CHEMISTRY REVIEW FOR END USE PRODUCTS

PRODUCT NAME: **Deltamethrin 4% Collar**
Company: **Roussel Uclaf Corp.**

TO: **13 George LaRocca/John Hebert**

FROM: **Shyam B. Mathur, Chemist** S Mathur 12/29/93

THRU: **Harold Podall, Section Head** H. Podall 12/29/93.

CHEMICAL: **097805 Deltamethrin**

MRID NOS. **Series 61(428935-01), Series 62(428935-02), Series 63(428935-03)**

Food Use( ) Non Food Use **(X)**

Inerts cleared: c ( ) d ( ) e ( ) yes **(X)** no ( )
Inerts List 1 ( ) Other ( )
NOTE: Inerts [redacted]
are not cleared. See ATTACHMENT-3.

Please provide the requested information for the following checked items:

1. [ ] Submit the specific chemistry data for your product.

[ ] If submitted earlier, provide MRID Number(s).

2. [ ] Your product is not sufficiently similar to the product you referenced.

3. In reference to the Confidential Statement of Formula (CSF), please provide the following information of your product:

   [ ] a) pH of a specified water dilution.

   [ ] b) Density

Inert ingredient information may be entitled to confidential treatment

CBI-4/SBM.

[ ] c) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate.

[ ] d) The upper and lower certified limits of the individually added inerts.

4. Based on the current CSF (**dated**), your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

5. Provide the chemical identify of all components, the percentage composition, CAS Registry Numbers, and Material Safety Data Sheet (two copies) for the following compounds:

6. In the proposed labeling, provide the following information:

[ ] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [ ] PR Notice 84-1 for non-aerosol containers for houses and institutional uses of [ ] PR Notice 83-3 for all other uses.

[ ] b) Add the heading to the label per 40CFR§172-6(a)1.

[ ] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as extremely Flammable (because your product contains flammable propellents). 40CFR§156.10(i)2(ix).

[ ] d) If the solvent has insecticidal activity provide the EPA Registration Number, if does not it should be removed from the active ingredient statement and added to the total percentage of the inert ingredients.

[ ] e) Add a footnote to the inert ingredients indicating: Contains petroleum distillates, xylene or xylene-range aromatic solvent.

[ ] f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the physical or Chemical Hazards heading;

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

[X] g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.

7. In reference to the product specific data requirements, provide the following information:

[ ] a) Statement of Composition: A complete description of the manufacturing formulation process. Describe equipment used, mixing time, temperature, pressure, etc. **The Registrant described the full formulation procedure for this product; the process, the quantities and the order of addition is described in Attachment-1. (MRID No. 428935-01)**

[ ] b) Discussion of Formation of Unintentional Ingredients: **The Registrant provided following information on this topic[MRID No.428935-01]: No unintentional inert ingredients are introduced in the blending or the filling processes. No unintentional inert ingredients are introduced by the market containers or by storage in them.**

[ ] c) Certification of Limits: Upper and lower limits or each active and individually added inert component. **The Registrant submitted a CSF (dated 08/11/93) for Basic formulation of the product.**

[ ] d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s). **The Registrant submitted data on Series 62 under MRID No. 428935-02). See Attachment-2.**

Series 63: MRID No. 428935-03

[ ] e) Color: In common terms: **White** **[SOP C-30]**

[ ] f) Physical State: **Solid** **[SOP C-31]**

[ ] g) Odor: **Odorless** **[SOP C-33]**

[ ] h) Density/Sp. Gravity: **72 lbs/cubic foot to 88 lbs/cubic foot [SOP C-35]**

[ ] i) pH: **Not Applicable. The product is not dispersible in water.**

[ ] j) Oxidizing or Reducing Action: **This product does not have the potential to act as a strong oxidizing or reducing agent.**

[ ] k) Explodability: **This product possesses no explosive potential.**

[ ] l) Viscosity: **Not Applicable, the product is a solid.**

[ ] m) Miscibility: **Not applicable as the product is not emulsifiable and is not intended to be diluted with both water and petroleum distillate.**

[X] n) Corrosion Characteristics: **The Registrant did not provide any data on this topic.**

[ ] o) Dielectric Breakdown Voltage: **NA as the product is not intended to be used around electrical equipment.**

Product ingredient source information may be entitled to confidential treatment

[X] p) Storage Stability: **The Registrant did not submit any data on this topic.**

[X] q) Flammability: **NA. The product is solid.**
NOTE: This needs further explanation

8. [ ] The following is the regulatory status of the inert ingredients under 40CFR 180.1001 for the exemption of the requirement of a tolerance.

9. Other

Note to PM: Inter-office

Please notify the Registrant :

(1). To correct the label as described in 6(g)[40CFR§156.10(g)]
(2). To submit data on Storage stability(7p) and corrosion characteristics (7n).
(3). To ask the Registrant whether the Flammability test was done with this product or not? The product being solid does not mean that it can not be Flammable.
(4). To use same units for temperature(C or F)during describing the formulation process(Series 61-2). Request them to provide information on it, mixed units were used when the process is described (MRID No. 428935-01).
(5). To correct the CAS No. of the AI Deltamethrin in the CSF submitted 8/11/93.

(6). [redacted]

(7). [redacted]

SUMMARY ATTACHED

TABLE 1: SUMMARY OF PRODUCT CHEMISTRY DATA REQUIREMENTS

GLR #	TITLES	
Series 61-Product Identity and Composition (40CFR158.155, 160, 162, 165 & 167)		
61-1	Product Identity & Disclosure of Ingredients	A
61-2	Description of Starting Materials & Manufacturing Process	A
61-3	Discussion of Formation of Impurities	A
Series 62-Analysis and Certification of Product Ingredients (40CFR158.170, 175 & 180)		
62-1	Preliminary Analysis of Product Samples	NA
62-2	Certification of Ingredient Limits	A
62-3	Analytical Methods to Verify Certified Limits	A
Series 63-Physical and Chemical Characteristics (40CFR158.190)		
63-2	Color	A
63-3	Physical State	A
63-4	Odor	A
63-5	Melting Point	NA
63-6	Boiling Point	NA
63-7	Density, Bulk Density, or Specific Gravity	A
63-8	Solubility	NA
63-9	Vapor Pressure	NA
63-10	Dissociation Constant	NA
63-11	Octanol/Water Partition Coefficient	NA
63-12	pH	A
63-13	Stability	NA

63-14	Oxidizing Or Reducing Action	A
63-15	Flammability	A(?)
63-16	Explodability	A
63-17	Storage stability	DG
63-18	Viscosity	NA
63-19	Miscibility	NA
63-20	Corrosion Characteristics	DG
63-21	Dielectric Breakdown Voltage	NA

A - Acceptable

W - Waived

NA - Not Applicable

DG - Data Gap

A(?) - Acceptable with Reservations

Reviewer_____

Section Head_____

Date: _____

Confidential Statement of Formula may be entitled to confidential treatment

ATTACHMENT-1

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

61-1. Product Identity & Disclosure of Ingredients
MRID No. 428935-01)

[redacted]	[redacted]

The Registrant submitted a CSF(Dated 8-11-93) which contains following inert ingredients not cleared by the agency:

[redacted]	[redacted]

ATTACHMENT-1 Contd....

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

61-2. Description of Beginning Material & Manufacturing Process
(MRID No. 428935-01)

Beginning Materials:

[redacted]

Manufacturing Process:

[redacted]

Manufacturing process information may be entitled to confidential treatment

ATTACHMENT-2

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

Series 62. (MRID No. 428935-02)

62-1. Preliminary Analysis This product is not produced by an integrated formulation system, therefore, preliminary analysis is not required [40CFR§158.170].

62-2. Certification of Ingredient Limits

See the CSF given in Series 61-1.

62-3. Analytical method to verify certified limits:

Determination of Deltamethrin in collars:

the amount of the AI in the collar is determined by using reversed phase HPLC system. A portion of the collar is sliced into very thin crossections, then extracted(using a Ultrasonic bath) with acidified acetonitrile. The solution was then filtered and injected into stabilized HPLC system. Results are quantified using peak area measurements with an external standard.

A suitable liquid chromatograph equipped with a UV detector and electronic integrator was used under isocratic conditions:
Column: Supelco LC-18, 25 cm length, 2.1 mm ID, 5 micron particle size.
Detector: 254 nm(UV wavelength)
Mobile Phase: 80% Mobile phase A[mix 99.8% acetonitrile and 0.2% glacial acetic acid and filter through 0.22 μ Nylon 66 filter and degas]

20% Mobile phase B[mix 99.8% deionized wtaer and 0.2% glacial acetic acid and filter through 0.22 μ Nylon 66 filter and degas].
Flow Rate: 0.35 ml/ min.
Chart speed: 0.5 cm/min.
Run time: 20 min.
Sample loop volume: 5 μl

ATTACHMENT-2 Contd....

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

Series 62. (MRID No. 428935-02)

Calculations:

$$\% \text{ Deltamethrin} = \frac{A_{sample} \times W_{std} \times P_{std}}{A_{std} \times W_{sample}}$$

A_{sample} = average peak area of deltamethrin in sample chromatogram

A_{std} = average peak area of deltamethrin in reference standard chromatogram

W_{std} = weight of deltamethrin standard

W_{sample} = weight of collar sample

P_{std} = % purity of deltamethrin standard.

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

ATTACHMENT 3

CR#: 93-05-18

REQUESTOR NAME: SHYAM B. MATHUR REQUEST DATE: 12/28/93

TEL.: ( ) 308-8378 ORG.: PCRS/RSB/RD ROOM: ____ MAIL CODE: H7505-W
(DIV./BR./SEC.)

CSF ATTACHED:

☒ YES If CSF is attached complete Item A and the chemical name in Item B.

☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:

✓Check Applicable Category

- ☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)
- ☒ Provide PCC for Non-Food Use Inert Ingredient (s)
- ☐ Provide PCC for Active Ingredient(s)
- ☐ Provide PCC for Dye
- ☐ Determine if Fragrance is Acceptable for Use in Formulation
- ☐ Other (Describe): _____

B. INGREDIENT INFORMATION:

[redacted]

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 432-TTD Product Name: Deltamethrin 4% collar

Registrant: Roussel Uclaf corporation Food-Use Pesticide: ☐ YES ☒ NO

Percent in Formulation (For Fragrance/Dyes only): 4%

INFORMATION REPORTED:

Ingredient No. 1:		Ingredient No. 2:	
PCC:		PCC:	New inert
TOL. STATUS:		TOL. STATUS:	
OTHER INF.:	Need specific Composition and CAS NOS. of the above trade name ingredient.	OTHER INF.:	
Ingredient No. 3:		**Ingredient No. 4:**	
PCC:		PCC:	
TOL. STATUS:		TOL. STATUS:	
OTHER INF.:	Need specific Composition and CAS NOS of the above trade name ingredient.	OTHER INF.:	

Completed By: LINDA FAN Date Completed: 01/03/94

*Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red FIFRA CBI cover should be affixed to the request form and the document handled accordingly.

Inert ingredient information may be entitled to confidential treatment

1595-030

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 23 1995

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Roussel Uclaf, S.A.,
Division Sante Animale
c/o Mr. John J. Lauber
Hoechst-Roussel Agri-Vet Company
Route 202-2026, P.O. Box 2500, Bedm. 31
Somerville, NJ 088760-1258

Dear Mr. Lauber:

Subject: Transfer of Pending Pesticide Registrations From Company Number 432 to Company Number 68451

Pursuant to your request in your letter and transfer agreement of February 14, 1995, we have approved the transfer of the following pending registrations from **AgrEvo Environmental Health, Inc.**, company number 432, to **Roussel Uclaf, S.A., Division Sante Animale**, company number 68451.

The effective date of these changes is the date of this letter.

Pending Product Name	Old EPA File Symbol	New EPA File Symbol
Deltamethrin 4% Collar	432-TTO	68451-R
Deltamethrin 3% Collar	432-TTI	68451-E

The products listed above are pending registrations and therefore cannot be marketed until they have been registered.

The transferred pending registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

By copy of this letter we are informing AgrEvo Environmental Health, Inc. of these changes. If you have any questions about this transfer please call Daria Mills at (703) 305-7406.

Sincerely,

John Jamula

John Jamula, Chief
Information Resources Section
Information Services Branch
Program Management and Support Div. (7502C)

cc: AgrEvo Environmental Health, Inc.

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[X] **Registration**
[ ] **Amendment**
[ ] **Other**

OPP Identifier Number: 201011

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
432-TTO	George LaRocca	[X] None [ ] Restricted
4. Company/Product (Name)	PM#	
Deltamethrin 4%-Collar	13	

5. Name and Address of Applicant *(Include ZIP Code)*

Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section II

[ ] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [ ] Other (Specify) _____
	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

* ***Certification must be submitted.***

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1.1 oz. (1 collar)	[X] On Label [ ] On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sharon M. Johnston	Registration Specialist	(201) 307-9700

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Sharon M. Johnston	Registration Specialist	Sharon M. Johnston	August 11, 1993

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number.**
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions (i.e., new products registration, resubmission, "me-too," reregistration, etc.

1. Self-explanatory.
2. EPA Use Only.

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 201011

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
432-TTO	George LaRocca	[X] None [ ] Restricted
4. Company/Product (Name)	PM#	
Deltamethrin 4% Collar	13	

5. Name and Address of Applicant *(Include ZIP Code)*

Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section II

[ ] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated _____.
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [ ] Other (Specify) _____
	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

* ***Certification must be submitted.***

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1.1 oz. (1 collar)	[X] On Label [ ] On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sharon M. Johnston	Registration Specialist	(201) 307-9700

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Sharon M. Johnston	Registration Specialist
4. Typed Name	5. Date
Sharon M. Johnston	August 11, 1993

Formulator's Exemption Statement

Applicant's Name and Address:

Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

EPA File Symbol/Registration Number: 432- TTO

Product Name: Deltamethrin 4% Collar

Date of Confidential Statement of Formula: August 11, 1993

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredient(s):

deltamethrin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another product.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source	
	Product Name	Registration Number
deltamethrin	[redacted]	[redacted]
Signature	Name and Title	Date
Sharon M. Johnston	Sharon M. Johnston Registration Specialist	August 11, 1993

Product ingredient source information may be entitled to confidential treatment

Certification with Respect to Citation of Data

Applicant's Name and Address:	EPA File Symbol/Registration Number: 432- TTO
Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645	Product Name: Deltamethrin 4% Collar Date of Application: August 11, 1993

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

   ☒ I am the original submitter*; or

   ☐ I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

   a. ☒ I am the original data submitter*; or

      ☐ I have obtained the written permission of the original data submitter to cite that study*; or

   b. ☐ I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

      ☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

      ☐ Those companies that have submitted the studies which I have cited (Selective method*)

   * A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature:	Name and Title:	Date:
Sharon M. Johnston	Sharon M. Johnston Registration Specialist	8-11-93

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature:	Name and Title:	Date:

DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD SUPPORT

1. Product Name: Deltamethrin 4% Collar	2. EPA Reg. No./File Symbol: 432- TTO	3. Formulator's Exemption Selected: YES X NO	4. Page 1 of 3
5. Applicant's Name and Address: Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645	6. Application for Registration Dated: 08 / 11 / 93 (MO. DAY YR.)	7. Name of Active Ingredient(s): Deltamethrin	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number
§158.150	PRODUCT CHEMISTRY							
61-1	Chemical Identity	X	08-11-93					
61-2	Begin. Materials & Manufacturing Process	X	08-11-93					
61-3	Discussion of Formation of Impurities	X	08-11-93					
62-1	Preliminary Analysis						NA (formualtor's exemption)	
62-2	Certification of Ingredient Limits	X	08-11-93					
62-3	Analytical Method to Verify Certified Limits	X	08-11-93					
63-2	Color	X	08-11-93					
63-3	Physical State	X	08-11-93					
63-4	Odor	X	08-11-93					
63-5	Melting Point						NA (formulator's exemption)	
63-6	Boiling Point						NA (formulator's exemption)	
63-7	Density, Bulk Density or Specific Gravity	X	08-11-93					
63-8	Solubility						NA (formulator's exemption)	

DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD SUPPORT

1. Product Name:	2. EPA Reg. No./File Symbol:	3. Formulator's Exemption Selected:	4. Page 2 of 3
Deltamethrin 4% Collar	432-TTO	YES X NO	
5. Applicant's Name and Address: Roussel Uclaf Corporation, 95 Chestnut Ridge Road, Montvale, NJ 07645	6. Application for Registration Dated: 08 / 11 / 93 (MO. / DAY / YR.)	7. Name of Active Ingredient(s): Deltamethrin	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number
§158.150	PRODUCT CHEMISTRY (Cont.)							
63-9	Vapor Pressure						NA (formulator's exemption)	
63-10	Dissociation Constant						NA (formulator's exemption)	
63-11	Octanol/Water Partition Coeffecient						NA (formulator's exemption)	
63-12	pH						NA (not dispersible with water)	
63-13	Stability						NA (formulator's exemption)	
63-14	Oxidizing/Reducing Action	X	08-11-93					
63-15	Flammability						NA (does not contain combustible liquids)	
63-16	Explodability	X	08-11-93					
63-17	Storage Stability						NA (PR Notice 92-5)	
63-18	Viscosity						NA (not a liquid)	
63-19	Miscibility						NA (not an emulsifiable concentrate)	
63-20	Corrosion Characteristics						NA (not corrosive)	
63-21	Dielectric Breakdown Voltage						NA (not for use around electrical equipment)	

DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD SUPPORT

1. Product Name:	2. EPA Reg. No./File Symbol:	3. Formulator's Exemption Selected:	4. Page 3 of 3
Deltamethrin 4% Collar	432-TTO	YES X NO	
5. Applicant's Name and Address:	6. Application for Registration Dated:	7. Name of Active Ingredient(s):	
Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645	08 / 11 / 93 MO. DAY YR.	Deltamethrin	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number
§158.340	TOXICOLOGY							
81-1	Acute Oral LD_{50} - Rat	X	07-09-93					
81-2	Acute Dermal LD_{50} - Rat/Rabbit	X	07-09-93					
81-3	Acute Inhalation LC_{50} - Rat	X	07-09-93				Waiver Request	
81-4	Primary Eye Irritation - Rabbit	X	07-09-93					
81-5	Primary Dermal Irritation	X	07-09-93					
81-6	Dermal Sensitization	X	07-09-93					
81-7	Acute Delayed Neurotoxicity - Hen						NA (not an organophosphate)	
86-1	Domestic Animal Safety	X	07-09-93					

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
✓	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA & TICK KILLERS AVAILABLE FOR USE ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

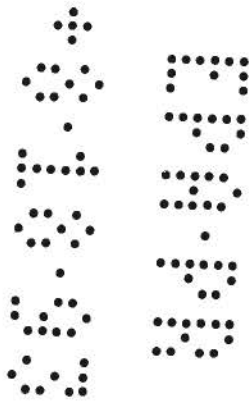
* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: **Keep out of reach of children**

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar
NET WT. 1.1 oz

EPA REG. NO. 432- EPA EST. NO. CODE



Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer
GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
CAUTION:
Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. **If in eyes,** flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

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STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE
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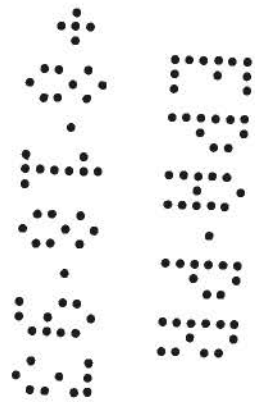

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
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ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

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See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar
NET WT. 1.1 oz

EPA REG. NO. 432- EPA EST. NO. CODE

Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer
GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
CAUTION:
Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

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Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

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FLEA & TICK COLLAR FOR DOGS

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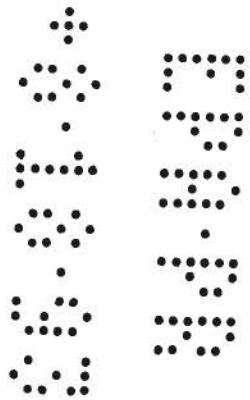

Roussel Uclaf Corporation
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Montvale, NJ 07645

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GUARANTEED 7 Month Tick Killer

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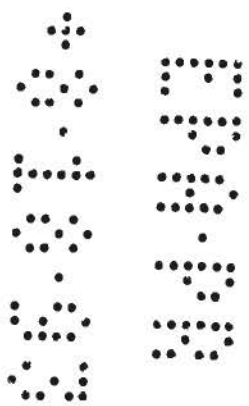

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NET WT. 1.1 oz

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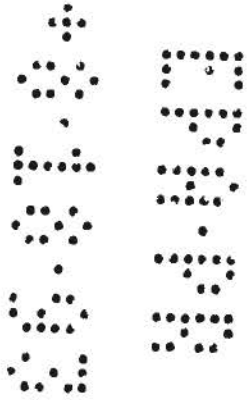

Roussel Uclaf Corporation
95 Chestnut Ridge Road
Montvale, NJ 07645

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

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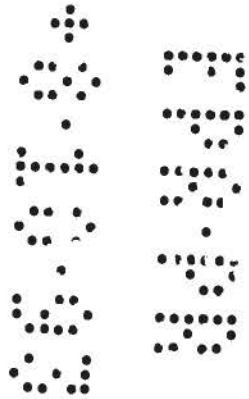

Pages 164-166 Confidential Statement of Formula may be entitled to confidential treatment